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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,891	06/17/2005	Johnathan A Napier	13478-00001-US	7537
23416 7590 01/23/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 01/23/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,891	Applicant(s) NAPIER ET AL.	
	Examiner Li Zheng	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's cancellation of claim 6, and amendments to claims 1-5 and 7-9 filed on 11/09/2007 are acknowledged.

As a result, claims 1-5 and 7-25 are pending.

Claims 10-25 are withdrawn for being drawn to non-elected inventions.

Claims 1-5 and 7-9 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objections to the specification are withdrawn in light of Applicants' amendments.

4. The objection to claim 1 is withdrawn in light of claim amendment.

5. All the rejections to claim 6 are withdrawn due to the cancellation of the claim.

6. The rejection of claims 1-9 under U.S.C 112, Second Paragraph, is withdrawn due to claim amendment.

7. The rejection of claims 1-9 under U.S.C 103(a) is withdrawn due to Applicants' argument.

Claim Rejections - 35 USC § 112

8. Claims 1-5 and 7-9 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed July 11, 2007. Applicants traverse in the paper filed November 9, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the nucleotide structure of the nucleotide sequences used in the claimed process is known in the art (response, page 10, last paragraph). However, only very limited number of genes encoding delta-5- and delta-8-desaturases are disclosed in the prior art and they are not considered be representative of the genus. Further, delta-9-elongase is not well known in the art at the time of the instant invention. Applicants rely on Applicants' own publication Qi et al for the support of written description. However, the alignment shown in Figure 2 of Qi et al. is not made

Art Unit: 1638

by using delta-9-elongases. Furthermore, the alignment indicates that there is only very limited homology among the elongases (page 161, last paragraph of the right column).

Applicants further argue that the present claims are not drawn to those delta-5- and delta-8-desaturases or delta-9-elongase per se but to a method using enzymes which were known and characterized in the art at the time of the filing. However, as discussed above, those gene are not well known in the art, especially for delta-9-elongase.

9. Claims 1-5 and 7-9 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for accumulate C20 polyunsaturated fatty acids in transgenic plant expressing nucleotide sequences encoding SEQ ID NO: 2,4 and 6, does not reasonably provide enablement for any transgenic plant expressing any delta-9-elongase, any delta-5- and delta-8-desaturase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed July 11, 2007. Applicants traverse in the paper filed November 9, 2007. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that gene for each type are known in the art and that the specification provides detailed guidance on how to identify and isolate structural genes and their functional homologs for the use in the claimed process for production of polyunsaturated fatty acids (response, page 12, 2nd paragraph). However, as

discussed above, the genes used in the claimed process are not well known especially for delta-9-elongase. Further, to identify and isolate those un-exemplified genes is undue without further guidance. Applicants argue that genes can be isolated by PCR or hybridization (response, page 12, 2nd paragraph). However, the conserved structure for delta-9-elongase is not known at all. To use claimed method to clone delta-9-elongase homologous gene is very unpredictable. Applicants argue that the art-recognized "histidine box sequences" are described to be advantageous for isolation of the structural genes useful for the claimed process(response, page 12, 2nd paragraph). However, as taught by Qi et al. that such histidine box is not specific to the genes of interest but found common to all membrane desaturases and other dioxy iron cluster protein (page 164, 2nd paragraph from the bottom of the left column) . Therefore, in contrast to Applicants' conclusion that to screening and testing delta-9-elongase, any delta-5- and delta-8-desaturase activity in plant is routine and is not undue experimentation, the Office maintains that undue experimentation is required for a person skilled in the art to clone un-exemplified genes encoding delta-9-elongase, any delta-5- and delta-8-desaturase by using PCR or hybridization, to verify its activity, to make the plant expression cassettes expressing all three genes, to transform plants therewith, and to confirm that the transgenic plants have the claimed content for all the compounds described in claim 1.

Still further, the working example in the specification only shows the data for the content of C20 polyunsaturated fatty acids such as the ones listed in table 1, it does not provide any evidence that other compounds in the formula I of claim 1 are produced by

Art Unit: 1638

the instant method. There is no evidence that the transgenically expressed enzymes would produce such unmanageable number of compounds as depicted in claim 1.

Applicants do not provide any response in this regard.

Summary

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

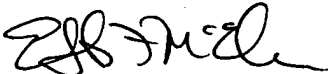
Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ELIZABETH MCELWAIN
PRIMARY EXAMINER